DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 31, 2014

JACE Medical LLC
Mr. Justin May
Director of Engineering
536 East 200 North
Warsaw, Indiana 46582

Re: K142484
Trade/Device Name: Sternal Closure System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC, JDQ
Dated: August 29, 2014
Received: September 4, 2014

Dear Mr. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K142484

Device Name
Sternal Closure System

Indications for Use *(Describe)*

The Sternal Closure System is intended for use in the stabilization and fixation of fractures of the sternum, including sternal fixation following sternotomy and sternal reconstructive surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Date:	29 August 2014
Sponsor:	JACE Medical, LLC 536 East 200 North Warsaw, IN 46582 USA (574) 527-1663
Contact Person:	Justin May, Director of Engineering
Trade Name:	Sternal Closure System
Common Name:	Cable/rod, plate and screw system
Device Classification:	Class II
Regulation, Name:	888.3010, Bone fixation cerclage 888.3030, Single/multiple component metallic bone fixation appliances and accessories 888.3040, Smooth or threaded metallic bone fixation fastener
Device Product Codes:	JDQ, HRS, HWC
Device Description:	The Sternal Closure System is comprised of bone screw, bone plate and fastener components and instruments for implantation. The plates are offered in a fixed one-piece and a fastenable two-piece style. Bone screws are available in a single diameter having a range of lengths. The interconnecting components come in solid and cable versions and fasten the halves of the two-piece plate.
Intended Use:	The Sternal Closure System is intended for use in the stabilization and fixation of fractures of the sternum, including sternal fixation following sternotomy and sternal reconstructive surgical procedures.
Materials:	The Sternal Closure System implant components are manufactured titanium alloy as described by ASTM F136.
Predicate Devices:	Biomet Microfixation Sternal Closure System (Biomet Microfixation: K110574, K111908, K121302) Ethicon Stainless Steel Suture Wire (Ethicon Inc.: K931271, K946173) Sternal Talon (KLS Martin, LP: K051165, K070169)
Performance Data:	Mechanical testing of the worst case Sternal Closure System constructs was performed in static and dynamic lateral distraction and static longitudinal shear. Sternal Closure System bone screws were evaluated according to ASTM F543. The mechanical test results demonstrate that the Sternal Closure System construct performance is substantially equivalent to the Ethicon Stainless Steel Suture Wire and that the Sternal Closure System screw performance is substantially equivalent to the Biomet Microfixation Sternal Closure System screws.

Technological Characteristics:

The Sternal Closure System possesses the same technological characteristics as the predicate devices. These include:

- performance,
- implant grade materials, and
- basic design.

Technological characteristics which are different have been supported with descriptive information and/or performance data. Therefore the fundamental scientific technology of the Sternal Closure System devices is the same as previously cleared devices.

Conclusion:

The Sternal Closure System possesses the same intended use and technological characteristics as the predicate devices. Therefore the Sternal Closure System is substantially equivalent for its intended use.